IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Kouji WAKI et al
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Title:	ULTRASONOGRAPH
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Examiner:	Hien Ngoc NGUYEN
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APPELLANTS' BRIEF

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Sir:

In response to the Notification of Non-Compliant Appeal Brief mailed September 16, 2011, and further to the Notice of Appeal filed on April 20, 2011, Appellants hereby resubmit their brief as follows. Appellants note that the last entered Amendment was dated November 4, 2010 and not May 3, 2010.

Real Party In Interest

The real party in interest is Hitachi Medical Corp., the assignee of the present application.

Related Appeals and Interferences

There are no known appeals or interferences that will directly affect or be affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

Claim 6 was previously cancelled.

Claims 11 and 12 have now been cancelled.

Claims 1-5 and 7-14 have been rejected.

Claims 1-5, 7-10, 13, and 14 are pending. This appeal involves each of these claims.

Status of Amendments

An Amendment under 37 CFR §41.37 is being submitted concurrently with the filing of the Appeal Brief. The Amendment cancels claims 11 and 12, and eliminates appeal of one of the grounds of rejection from the final Office Action mailed January 20, 2011.

Summary of Claimed Subject Matter

The present invention relates to an ultrasonic imaging apparatus which utilizes ultrasonic waves to obtain an ultrasound image of a diagnostic portion of an object. The apparatus allows an elastic image to be displayed with the strain on the tissue or the elastic modulus.

According to independent claim 1, for example, the ultrasonic imaging apparatus (see Fig. 1) includes an ultrasonic probe (2) that sends and receives ultrasonic waves

to/from an object (1). See page 8, line 19 to page 11, line 2. An ultrasound image structuring unit (6) is configured to generate an ultrasound image based on a reflected echo signal that is received by the ultrasonic probe. See page 8, line 19 to page 9, line 23 and page 11, line 3 to page 12, line 1. An elastic image structuring unit (7) is configured to obtain a strain or an elastic modulus of the object in a region corresponding to the ultrasound image based on the reflected echo signal and generate a color elastic image. See page 12, lines 2-13. The ultrasonic imaging apparatus further includes a display (9) configured to overlay the ultrasound image to the color elastic image or arrange the ultrasound image and the color elastic image, and subsequently display the resultant image on a screen. See page 19, lines 15-23; page 30, line 22 to page 31, line 10; abstract; and Fig. 3. A setting unit (17) is also configured to variably set a corresponding relationship between a hue of the color elastic image displayed on the screen and a level of the strain or elastic modulus. See page 12, lines 2-13 and abstract. According to independent claim 1, the color elastic image is displayed with the hue for a larger region or a smaller region in the strain or the elastic modulus than a preset amount of the strain or the elastic modulus. See page 20, line 9 to page 21, line 13.

The present invention advantageously allows the assignment the hue information in the color conversion table 31 to be selected, thereby preventing the display operation of a neutral portion 33. Specifically, an instruction is input to the boundary line control portion 22 from the operating unit 17 and the hue information in the color conversion table 31 is changed, thereby extracting only a hard region and a soft region with desired strain and only a region with high elastic modulus and a region with low elastic modulus. Such features further enable the elastic image to be displayed with the removal of noise in the unnecessary data. Additionally, it becomes possible to display either the hard region or

the soft region with strain, or to display either the region with high elastic modulus or the region with low elastic modulus. See page 27, line 24 to page 29, line 20.

According to independent claim 14, the ultrasonic imaging apparatus includes an ultrasonic probe (2) that sends and receives ultrasonic waves to/from an object (1), an ultrasound image structuring unit (6) configured to generate an ultrasound image based on a reflected echo signal that is received by the ultrasonic probe, and an elastic image structuring unit (7) configured to obtain a strain or an elastic modulus of the object in a region corresponding to the ultrasound image based on the reflected echo signal and generate a color elastic image. See page 8, line 19 to page 12, line 13. A display (9) is configured to overlay the ultrasound image to the color elastic image or arrange the ultrasound image and the color elastic image, and subsequently display the resultant image on a screen. See page 19, lines 15-23; page 30, line 22 to page 31, line 10; abstract; and Fig. 3. A setting unit (17) is also configured to variably set a corresponding relationship between a hue of the color elastic image displayed on the screen and a level of the strain or elastic modulus. See page 12, lines 2-13 and abstract. The setting unit assigns the hue of the color elastic image so that the display is prevented from displaying a neutral portion (33) in a color conversion table. See page 27, line 24 to page 29, line 20.

Grounds of Rejection to be Reviewed on Appeal

I. Whether Claims 1, 9, and 14 are unpatentable under 35 U.S.C. §102(b) over U.S. Patent No. 6,068,597 issued to Lin

Argument

Claims 1, 9, and 14 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lin. Claims 2-5, 7, 8, and 10-13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lin in view of Miga. For the reasons set forth below, these rejections should be reversed.

Claims 1, 9, and 14 are not anticipated by Lin. The rejection of these claims under 35 U.S.C. §102(b) is improper, because the Office Action has failed to properly interpret all the limitations recited in the claims, and consequently, failed to make a prima facie case of anticipation.

Independent claim 1

Turning now to the instant invention, independent claim 1 defines an ultrasonic imaging apparatus capable of displaying an ultrasound image of a diagnostic portion of an object together with the strain or elastic modulus. The ultrasonic imaging apparatus comprises:

> an ultrasonic probe that receives and sends ultrasonic waves from/to an object;
>
> an ultrasound image structuring unit configured to generate an ultrasound image on the basis of a reflected echo signal received by the ultrasonic probe;
>
> an elastic image structuring unit configured to obtain a strain or an elastic modulus of the elasticity of the object of a region corresponding to the

ultrasound image on the basis of the reflected echo signal and generates a color elastic image;

a display configured to overlay the ultrasound image to the color elastic image, or arrange the ultrasound image and the color elastic image and displays the resultant image on a screen; and

a setting unit configured to variably set a corresponding relationship between a hue of the color elastic image displayed on the screen and the level of the strain or elastic modulus, wherein

the color elastic image is displayed with the hue for a larger region or a smaller region in the strain or the elastic modulus than a preset amount of the strain or the elastic modulus.

The Office Action asserts that Lin discloses an elastic image structuring unit as set forth in independent claim 1. In support of this assertion, the Office Action directs reference to column 2, lines 40-49; column 3, lines 13-43; and indicates that the processors and scan converter of Lin receive echo signals and generate color elastic images. The cited passage, however, merely indicates that vibrational Doppler imaging (VDI), can provide elastographic information based on induced vibration at a given frequency and power color Doppler imaging of induced tissue motion. While VDI provides improved spatial and contrast resolution, VDI images contain a mixture of acoustic reflectivity, tissue elasticity, and vibrational resonance information. This can result in diagnostic ambiguity, depending on the chosen vibrational frequency. See column 2, lines 40-49. Lin goes on to indicate that the vibrational resonance spectrum can be displayed for a graphically-defined region of interest. Alternatively, vibrational resonance spectra are acquired at each of a plurality of locations in an image, curve shape criteria are applied to differentiate the vibrational resonance characteristics at each location, and the resulting values are mapped into different colors in a two-dimensional space to provide a

vibrational resonance image. See column 3, lines 29-40. There is nothing in the cited passage to suggest that Lin obtains a strain or an elastic modulus of the elasticity of the object of a region corresponding to the ultrasound image. There is also nothing to suggest that a color elastic image is generated based on the strain or elastic modulus.

Next, the Office Action asserts that Lin discloses a setting unit, and directs attention to column 7, line 47 to column 8, line 11. The Office Action indicates that Lin discloses adjustment of the "color window to create accurate color image that enable viewer to differentiate tumor from soft tissue." See page 3, lines 13-14. This assertion appears to contradict the express teachings of the cited passage. First, neither the cited passage nor claim 4 provides such disclosure. While there is a discussion pertaining to sequencing of vibrational and ultrasonic imaging in the passage, it is unrelated to variably setting any type of relationship between a hue of the color elastic image and the level of the strain or elastic modulus. The cited passage merely indicates that a spatial mean power estimator 730 computes the mean Doppler power in each ROI, and a spectrum buffer 732 accumulates data points from each ROI for each respective spectrum. A curve shape estimator 834 generates the quantitative indices used by a pixel encoder/interpolator 852 to assign values to center pixels in each ROI using predefined curve shape criteria, and a pixel interpolator fills in pixel values in between neighboring center pixels. Encoded values at each pixel in the vibrational resonance ultrasonic Doppler image are mapped into colors and displayed as a color image on the monitor 138. There is nothing to suggest disclosure of a setting unit, as set forth in independent claim 1, and no mention of a relationship between a hue of the color elastic image and a level of the strain or elastic modulus.

The Office Action also asserts that Lin discloses a color elastic image which is displayed with the hue for a larger region or a smaller region in the strain or the elastic

modulus than a preset amount of the strain or the elastic modulus. Reference is directed to column 2, line 50 to column 3, line 10 and column 4, lines 14-18. See page 4, lines 5-9. Review of the cited passage, however, suggests that Lin is disclosing something altogether different. According to the Applicants, the brief description of Fig. 9 merely indicates that the Figure illustrates how an exemplary set of curve shape criteria can be applied to a vibrational resonance (or frequency) spectrum to generate a color mapping according to one embodiment of the present invention. See column 4, lines 14-18.

There is no suggestion for the features alleged in the Office Action. Lin goes on to indicate that FIG. 9 illustrates a typical vibrational resonance (or frequency) spectrum 910 from living tissue, and provides exemplary spectral peaks a and c, -6 dB bandwidth points c- and c+ of the main peak, valley b, and a selected frequency point d. Curve shape criteria may be quantified in terms of various attenuation-independent parameters based on such spectrum features. See column 8, lines12-18. According to the Applicants, Fig. 9 is intended to illustrate how an exemplary set of curve shape criteria can be applied to a vibrational resonance (or frequency) spectrum to generate a color mapping. As can be clearly seen, this figure is completely different and unrelated to, for example, Fig. 6 of the present invention.

Lin appears to display all resulting values mapped into different colors. Since all resulting values with different colors are displayed, it is possible to assign a hue value to all regions, including a medium region. The medium region is not a harder or softer region. It is defined as an unnecessary region. However, displaying all of the resulting values with a hue results in distractions for the operator and reduces the level of focus and concentration that would be placed on harder regions such as tumors. According to the Applicants, the cited passage (and the reference in general) appears to be concerned with the use of vibrational frequencies to identify vibrational resonance (or frequency)

signatures capable of improving the sensitivity and specificity of the ultrasound images. See column 3, lines 1-10.

Contrary to the present invention, Lin does not use the strain or elastic modulus as a parameter for generating the ultrasound image. Consequently, it is not possible for Lin to disclose a preset amount that is based on the strain or elastic modulus. Lin also relies solely on the vibrational frequency, which cannot be adjusted based on the hardness and prevents any adjustments based on a preset amount. The frequency in Lin is not a parameter for an operator to use in order to acquire the hardness intuitively. According to Lin, it is difficult for the operator to set a threshold based on the frequency. In contrast, the ultrasonic imaging apparatus defined by independent claim 1 is configured to display the color elastic image with the hue for a larger region or a smaller region in the strain or the elastic modulus than a preset amount of the strain or the elastic modulus. Thus, the ultrasonic imaging apparatus is capable of displaying the color elastic image with only the required hardness regions (i.e., excluding any unnecessary regions from the image). Lin provides no disclosure or suggestion for displaying the color elastic image in the manner set forth in independent claim 1.

The Office Action appears to broadly interpret the cited passages as reading on claimed features. As discussed above, however, there appears to be no relationship to the claimed features. The only way that such features can be interpreted as reading on the claims is through impermissible hindsight. Lin is completely silent on measurement of the strain and elastic modulus of tissue in the region of interest, and displaying a color image visually illustrating a relationship between such measurements and the hue of the color. According to the present invention, for example, both the tomographic image and elastic image are displayed for the harder region, while only the tomographic image is displayed for the medium region. Therefore, the spread of harder region, such as a tumor,

corresponding to the tomographic image and elastic image is displayed clearly for the operator to acquire the spread of harder region.

Lin simply fails to provide any disclosure for various features recited in independent claim 1. Accordingly, anticipation of independent claim 1 by Lin is believed to be improper under 35 U.S.C. §102(b).

Dependent Claims 2-5, 7-10, and 13

Dependent claims 2-5, 7-10, and 13 stand and fall together with independent claim 1.

Independent claim 14

Independent claim 14 defines an ultrasonic imaging apparatus that comprises:

an ultrasonic probe that receives and sends ultrasonic waves from/to an object;

an ultrasound image structuring unit configured to generate an ultrasound image on the basis of a reflected echo signal received by the ultrasonic probe;

an elastic image structuring unit configured to obtain a strain or an elastic modulus of the object of a region corresponding to the ultrasound image on the basis of the reflected echo signal and generate a color elastic image;

a display configured to overlay the ultrasound image to the color elastic image, or arranges the ultrasound image to the color elastic image and display the resultant image on a screen; and

a setting unit configured to variably set a corresponding relationship between a hue of the color elastic image displayed on the screen and a level of the strain or the elastic modulus, wherein

the setting unit assigns the hue of the color elastic image so as to prevent the display from displaying a neutral portion in a color conversion table.

In support of the rejection of independent claim 14, the Office Action asserts, in part, that Lin discloses a setting unit and that the setting unit assigns the hue of the color elastic image so as to prevent the display from displaying a neutral portion in a color conversion table. Reference is directed to column 9, lines 8-49.

As discussed with respect to independent claim 1, however, Lin fails to provide any disclosure or suggestion for a setting unit as set forth in the claimed invention. The cited passage, however, also fails to disclose the feature alleged in the Office Action. Lin merely indicates that operator settings can be made for vibrational frequency range, vibrational frequency step intervals, ROI size, Doppler acquisition parameters, selection of curve shape criteria, color mapping scheme, etc. Parallel sequences of vibrational stimulation and ultrasonic pulse transmission, as well as a sequence of power Doppler vector generation from echoes received from vibrating structures or tissues, are initiated. Lin subsequently performs color scan conversion and computation of the spatial mean Doppler amplitude. Lin goes on to normalize the previously-specified color maps to maximum index values and encodes characteristic indices into pixels in the color frame buffer so that a vibrational resonance image is displayed on the monitor. Lin appears to be completely silent on assigning the hue of the color elastic image so that the display is prevented from displaying a neutral portion in a color conversion table.

The Office Action further indicates that the claim is interpreted as setting a neutral region between two regions to RGB/000 which is black, and that the operator is capable of setting the boundary region between two regions to black. This appears to be a misinterpretation of both the claims and the reference. First, Lin fails to provide any

disclosure or suggestion for setting a specific region to black. Furthermore, the claimed invention does not assign a color of black to any specific region. Rather, claimed invention omits assignment of a hue value to the region. By omitting a hue value to a medium region, for example, the ultrasonic imaging apparatus of independent claim 14 is capable of providing a tomographic image which includes an elastic image of the required hard and soft regions, while excluding an elastic image of the medium region. Accordingly, an operator can easily identify and understand the region containing a tumor. Lin fails to provide any disclosure or suggestion for such features.

Accordingly, anticipation of independent claim 14 by Lin is believed to be improper under 35 U.S.C. §102(b).

CONCLUSION

For the foregoing reasons, the final rejection of the claims should be reversed.

FEES

The Appeal Brief fee has been previously submitted.

AUTHORIZATION

Please charge any shortage in fees due in connection with the filing of this Notice of Appeal, including extension of time fees, to Deposit Account No. 01-2135 (Docket. No. 389.46211X00) and please credit any excess fees to such deposit account.

Respectfully submitted,
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CLAIMS APPENDIX

1. An ultrasonic imaging apparatus comprising:

an ultrasonic probe that receives and sends ultrasonic waves from/to an object;

an ultrasound image structuring unit configured to generate an ultrasound image on the basis of a reflected echo signal received by the ultrasonic probe;

an elastic image structuring unit configured to obtain a strain or an elastic modulus of the elasticity of the object of a region corresponding to the ultrasound image on the basis of the reflected echo signal and generates a color elastic image;

a display configured to overlay the ultrasound image to the color elastic image, or arrange the ultrasound image and the color elastic image and displays the resultant image on a screen; and

a setting unit configured to variably set a corresponding relationship between a hue of the color elastic image displayed on the screen and the level of the strain or elastic modulus, wherein

the color elastic image is displayed with the hue for a larger region or a smaller region in the strain or the elastic modulus than a preset amount of the strain or the elastic modulus.

2. An ultrasonic imaging apparatus according to Claim 1, wherein the corresponding relationship between the hue of the color elastic image and the level of the strain or elastic modulus set by the setting unit is displayed on the screen with a color bar.

3. An ultrasonic imaging apparatus according to Claim 2, wherein, with the color bar, a large amount of the strain or the elastic modulus and a small amount of the strain or the elastic modulus are displayed with different hues and the boundary between the hue having the large amount of the strain or the elastic modulus and the hue having the small amount of the strain or the elastic modulus is displayed with another hue.

4. An ultrasonic imaging apparatus according to Claim 3, wherein the boundary between the hue having the large amount of the strain or the elastic modulus and the hue having the small amount of the strain or the elastic modulus is movably formed with the setting unit.

5. An ultrasonic imaging apparatus according to Claim 2, wherein a boundary region of the hue different from the hue of the periphery is settably formed at an arbitrary position of the color bar with the setting unit.

7. An ultrasonic imaging apparatus according to Claim 1, wherein the color elastic image has a peripheral region including a setting value of the amount of the strain or the elastic modulus with the hue different from the hue of another region.

8. An ultrasonic imaging apparatus according to Claim 7, wherein the hue of the peripheral region has a tone in accordance with the level of the amount of the strain or the elastic modulus.

9. An ultrasonic imaging apparatus according to Claim 1, wherein the elastic image structuring unit comprises:

a color conversion table that is rewritable and sets a relationship between the level of the amount of the strain or the elastic modulus and the color of the color elastic image;

a calculator configured to calculate an amount of the strain or the elastic modulus of the elasticity of the object of a region corresponding to the ultrasound image on the basis of the reflected echo signal and; and

a color image generator configured to read the color corresponding to the obtained amount of the strain or the elastic modulus from the conversion table and generate a color elastic image indicating the distribution of physical quantities, and

wherein the color conversion table is rewritten in accordance with an instruction input from the setting unit.

10. An ultrasonic imaging apparatus according to Claim 9, wherein the elastic image structuring unit displays, on the screen of the display unit, a color bar indicating a corresponding relationship between the level of the amount of the strain or the elastic modulus and the hue of the color elastic image, set to the color conversion table.

13. An ultrasonic imaging apparatus according to Claim 1, wherein the color elastic image is displayed for at least one of a hard region with a high elastic modulus and a soft region with a low elastic modulus.

14. An ultrasonic imaging apparatus comprising:

an ultrasonic probe that receives and sends ultrasonic waves from/to an object;

an ultrasound image structuring unit configured to generate an ultrasound image on the basis of a reflected echo signal received by the ultrasonic probe;

an elastic image structuring unit configured to obtain a strain or an elastic modulus of the object of a region corresponding to the ultrasound image on the basis of the reflected echo signal and generate a color elastic image;

a display configured to overlay the ultrasound image to the color elastic image, or arranges the ultrasound image to the color elastic image and display the resultant image on a screen; and

a setting unit configured to variably set a corresponding relationship between a hue of the color elastic image displayed on the screen and a level of the strain or the elastic modulus, wherein

the setting unit assigns the hue of the color elastic image so as to prevent the display from displaying a neutral portion in a color conversion table.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None